



Medicines Control Authority of Zimbabwe

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Medicines Control Authority

EVALUATIONS AND REGISTRATION DIVISION

TITLE: Standard Operating Procedure for Issuing a Marketing Authorisation Certificate of a Medicinal Product (Human Complementary Medicines).			
SOP Number: EVR 33		Revision Number: 0 Document Level: 3	
Date Issued for training: 09/09/2025		Effective Date: 17/09/2025	
Page 1 of 10		Review Date: 09/12/27	
Written by:	P. ZVAREVASHE Name	P. Zvarevashe Signature	08/09/2025 Date
Approved by HoU/HoD:	M. G. MATIMBA Name	M. G. Matimba Signature	28/09/2025 Date
Authorised for use by: (Quality Manager)	A. Chikwara Name	A. Chikwara Signature	17/09/2025 Date

1.0 PURPOSE

To enable a Regulatory Officer to successfully issue a marketing authorisation certificate of a human complementary medicinal product

2.0 SCOPE

This procedure shall be performed by a Regulatory Officer when preparing a marketing authorisation certificate for a human complementary medicine after approval of such a product by the Complementary Medicines Sub-Committee.

3.0 FREQUENCY

Whenever a new application for marketing authorisation has been approved by the Complementary Medicines Sub-Committee.

4.0 LOCATION

- 4.1 The Master Copy of this SOP is kept by the Quality Office.
- 4.2 Controlled copies are kept by the Head of Evaluations & Registration Division and Evaluations & Registration Division staff.
- 4.3 Controlled copies issued to staff will be kept at points of use in the division.

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5.0 DEFINITIONS

- 5.1 **CMA Book "EVR12":** The current Medicines Register in which all approved Complementary medicines (Human and Veterinary) are recorded.
- 5.2 **Application file:** A collection of documents which are submitted as an application for registration of a medicine.
- 5.3 **Application Number:** An alpha-numeric number used as a reference code for a particular new (pending), application in the ZIMDIS programme, prior to registration. This number is used from the date of receipt of the application to the date of issue of a registration certificate. A numeric number used as a reference code for a particular registered product in the ZIMDIS programme.
- 5.4 **Applicant:** The person by whom or on whose behalf, an application for registration is made.
- 5.5 **Trade Name:** The proprietary name given to the product by the applicant
- 5.6 **Generic Name:** The WHO-recommended international non-proprietary name (rINN) for an active pharmaceutical ingredient that is generally accepted as the official name.
- 5.7 **MC8:** Application form for registration of a medicine (human allopathic and veterinary medicines)
- 5.8 **CM1:** Application form for registration of a complementary medicine
- 5.9 **CM2:** Approval certificate for complementary medicines (Human and Veterinary)

6.0 RESPONSIBILITY

- 6.1 The Regulatory Officer or their designate is responsible for preparing and issuing the marketing authorisation certificate.
- 6.2 The Chief Regulatory Officer and/or Head- EVR or their designates verify the correctness of the marketing authorisation certificate.
- 6.3 Director-General signs and endorses the certificate with an embossed seal.
- 6.4 The Head of Division has the overall responsibility of ensuring that this procedure is always adhered to.
- 6.5 The Quality Manager/Designate shall be responsible for monitoring compliance to the procedure, Quality Management System, relevant national and international standards.

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Date: 08/09/2025	Date: 03/09/2025	Date: 17/09/2025

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7.0 PROCEDURE

7.1 **Preparations for Issue of a Marketing Authorisation certificate**

- 7.1.1 Retrieve the product application file and cross-check whether all previous issues raised with respect to document review, laboratory analysis, GMP inspection have been resolved.
- 7.1.2 Check whether the Complementary medicines sub-Committee has approved marketing authorisation of the product (refer to the minutes of the Committee meeting).
- 7.1.3 Cross-check the recorded conditions for registration of the product recorded in the minutes.
- 7.1.4 Verify whether the applicant has accepted, in writing, the proposed conditions of marketing authorisation.
- 7.1.5 If the applicant objects to the proposed registration conditions table the applicant's appeals in the next meeting of the Complementary medicines sub-Committee.
- 7.1.6 If the applicant has accepted the conditions, fill in the approval certificate template (CM2) using information from the most recent CM1 application form in the product file and the conditions of approval recorded in the minutes and accepted by the applicant.

7.2 **Entering the product information of the product in the EVRB12 "CMA-Book" for human complementary medicines and Veterinary Complementary Medicines (new certificate only).**

- 7.2.1 Enter a file number, i.e., next number in sequence.
- 7.2.2 Record the product's application number.
- 7.2.3 Record the product's approved name
- 7.2.4 Record the date of approval.
- 7.2.5 Record the dosage form of the product (e.g., tablet, capsule, solution etc.)
- 7.2.6 Enter the approval number which has 2 parts separated by a forward slash e.g. (20xx/CMxxxx), where the first part is the year of approval, and the last part is the file number which is cumulative.
- 7.2.7 Record the name of the applicant.
- 7.2.8 Enter the category for distribution as recorded in the Complementary Medicines sub-Committee meeting minutes and verify with Section 8 of **SI 97 of 2015 Third Schedule** 'Categories for The Distribution of Complementary Medicines'.
- 7.2.9 Enter the shelf life approved by the Committee, in months. Double check whether this is the same as recorded in the evaluation report and accepted by the applicant.

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Date: 08/09/2025	Date: 08/09/2025	Date: 17/09/2025

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7.3 Completing the Approval Certificate Template (CM2) for Human Complementary and Veterinary Complementary Medicines

- 7.3.1 Enter the file number allocated from file EVRB12“CMA Book”.
- 7.3.2 Record the product’s approved name.
- 7.3.3 Record the trade name.
- 7.3.4 Record the dosage form and colour as described on the CM1 form.
- 7.3.5 Record the approved name of the active ingredient(s) and strength.
- 7.3.6 Record the approval number as allocated in the CMA book.
- 7.3.7 Record the shelf-life in months, packaging, and the storage conditions (e.g., 36 months below 30°C when packed in HDPE bottle).
- 7.3.8 Record the category for distribution.
- 7.3.9 Enter the name and physical address of the manufacturer(s) as stated on the CM1 form.
- 7.3.10 Enter the name and address of the principal as declared on the CM1 form.
- 7.3.11 Enter the name and address of the applicant as declared on the CM1 form.
- 7.3.12 Enter the address where the certificate would be kept. This is the same as the details of the declared applicant in the CM1 form.
- 7.3.13 Enter the date of registration, date on which an entry was made in the EVRB12 “CMA-Book”.
- 7.3.14 Record whether the product would be **wholly manufactured in**, or **imported into**, or **partially manufactured in** Zimbabwe, check the CM1 form.
- 7.3.15 Record the conditions imposed by the Authority, for all products: *See annexure NB: the annexure details the following*
- i. **General Conditions** (herewith underlisted)
 1. Compliance with labelling requirements.
 2. Subject to renewal of registration every five (5) years on condition of demonstration of quality, safety, and efficacy.
 3. Mandatory Reporting of Individual Case Safety Reports (ICSRs) that includes (ADRs, AEs, SAEs, & AEFIs) and/or product defects.
 4. Applicant and/or manufacturer is required to have a functional Pharmacovigilance system in place for their medical products.
 5. Applicant and/or manufacturer is required to designate a responsible person for Pharmacovigilance (QPPV) to be in charge of the pharmacovigilance system for the applicant.
 6. Periodic Safety Update Reports (PSURs) and Periodic Benefit Risk Evaluation Reports (PBERs) are generated for innovator products and biological products. For generic products, these should be generated if there are safety concerns.
 7. Compliance with any request by the Authority to conduct post-authorisation safety and efficacy studies whenever the need may arise.
 - ii. **Product Specific conditions** (herewith underlisted)
 1. Approved label

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Date: 08/09/2025	Date: 08/09/2025	Date: 08/09/2025

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- 7.3.16 Record the date of issue of certificate. This should be the same as the date of entry in CMA-Book for new products.
- 7.3.17 Record the date of issue of the certificate (date of signing) which is the same as date as in 7.3.16.
- 7.3.18 Compare the information on the certificate with that in the ZIMDIS and Evaluation report for correctness.
- 7.3.19 Send the certificate, checklist form for correctness of information on certificates "EVRF25", and updated MC8 form to the second reviewer Senior Regulatory Officer, Chief Regulatory Officer or Head-EVR or their designate for the initial review.
- 7.3.20 Send the certificate, checklist form for correctness of information on certificates "EVRF25", and updated MC8 form to the Chief Regulatory Officer or Head-EVR or their designate for the final review.
- 7.3.21 Send the reviewed certificate to the Director-General's office for signing and seal.
- 7.3.22 Make a photocopy of the signed certificate, quote the alpha-numeric application number at the top-right corner of the registration certificate, and send it to the product file in the filing room. Upload the scanned copy on SharePoint.
- 7.3.23 Send the certificate and cover letter for registration to the applicant. The standard operating procedure for correspondence with clients (**SOP EVR16**) should be followed.

7.4 Preparations for Issue of a Marketing Authorisation certificate for reinstatements

- 7.4.1 Retrieve the product reinstatement application file and cross-check whether all previous issues raised with respect to document review, laboratory analysis, GMP inspection have been resolved.
- 7.4.2 Check whether the Complementary Medicines Sub-Committee approved the reinstatement of the product. (refer to the minutes of the Complementary Medicines Sub-Committee meeting).
- 7.4.3 Cross-check the recorded conditions for reinstatement of the product recorded in the minutes.
- 7.4.4 Verify that all approved variations (if any) have been included in the application. Unapproved variations will not be incorporated and approved in the reinstatement application.
- 7.4.5 Verify whether the applicant has included a revised (if applicable), signed, and dated CM1 form, incorporating the approved variations, if any were submitted for that application. If the CM1 form was not revised due to variations, ensure that the details at approval of the product application are still the same as submitted in the submitted CM1 form.

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Date: 08/09/2025	Date: 08/09/2025	Date: 17/09/2025

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- 7.4.6 If the applicant has not provided a revised CM1 form, communicate with the applicant via email. The Chief regulatory Officer should be copied in all emails sent to clients as per **SOP EVR 16**.
- 7.4.7 If the applicant has provided a revised (if applicable) CM1 form, fill-in the approval certificate template CM2 using information from the most recent CM1 application form in the product file and the conditions of marketing authorisation recorded in the minutes and accepted by the applicant.
- 7.4.8 Complete the approval certificate template and where applicable, incorporate any necessary changes.
- 7.4.9 Record the date of issue of the certificate (date of signing).
- 7.4.10 Compare the information on the certificate with that in ZIMDIS and Evaluation report for correctness.
- 7.4.11 Follow steps 7.3.19 to 7.3.21
- 7.4.12 Make a photocopy of the signed certificate, quote the alpha-numeric application number at the top-right corner of the marketing authorisation certificate, and send it to the product file in the filing room. Upload a scanned copy on SharePoint. Ensure that the product database is updated with the new expiry date.
- 7.4.13 Send an email notification for the availability of the new and revised certificate to the applicant. When sending the certificate to the applicant the regulatory officer shall advise the applicant to return the previous certificate before the authority can provide them with the new certificate.
- 7.4.14 The regulatory officer shall take the revised marketing authorisation certificate and cover letter to main gate reception, upon being given the old certificate the regulatory officer shall enter in the EVR main gate client correspondence book details of the revised certificate to be collected.

8.0 APPENDICES/ ATTACHMENTS

- 8.1 Appendix I: Completed CM2 template
- 8.2 Attachment I: Checklist form for correctness of information on certificates EVRF25

Written by: <i>MD Mavaga</i>	Approved by HoU/HoD: <i>MD Mavaga</i>	Authorised for use by QM: <i>MD Mavaga</i>
Date: <i>08/09/2025</i>	Date: <i>08/09/2025</i>	Date: <i>08/09/2025</i>

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9.0 RECORDS

Document Number	Title of Record	Retention Period
N/A	Copy of registration certificate	Infinity
N/A	ZIMDIS database in computer	Infinity
EVRB02	Entry in C-Book	Infinity
EVRB12	Entry in CMA-Book	Infinity
EVRB16	Entry in H Book	Infinity
N/A	Cover letter for Registration Certificate	Infinity
EVRF25	Checklist form for correctness of information on certificates	Infinity

10.0 REFERENCES

- 10.1 SOP MR 4.0 Writing Standard Operating Procedure
- 10.2 SOP MR 4.13 Control of Records
- 10.3 SOP EVR 16 Procedure for Correspondence with Clients

11.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change
N/A	N/A	N/A

Written by: <i>P. Murewa</i>	Approved by HoU/HoD: <i>P. Murewa</i>	Authorised for use by QM: <i>P. Murewa</i>
Date: 08/09/2025	Date: 08/09/2025	Date: 17/09/2025

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Appendix I: Completed CM2 template

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**Medicines and Allied Substances (Complementary Medicines) Regulation
(S.I. 97 of 2015)**

APPROVAL CERTIFICATE

CONFIDENTIAL

Number: CM0411

It is hereby notified that a Complementary Medicine has been approved as follows:

1. Approved name of Complementary Medicine: IRON (AS FERROUS FUMARATE) /ZINC (AS ZINC SULPHATE) /COPPER (AS COPPER SULPHATE) /FOLACIN (AS FOLIC ACID) /VITAMIN B12 /VITAMIN B6
2. Trade name of Complementary Medicine: HEALTH 1st FEROCAP CAPSULES
3. The form in which the Complementary Medicine is presented and the colour thereof: CLEAR HARD GELATIN CAPSULE SIZE "1" FILLED WITH YELLOW AND BROWN COLOURED PELLETS.
4. Active ingredient(s) and strength: IRON (AS FERROUS FUMARATE) 24MG /ZINC (AS ZINC SULPHATE) 12MG /COPPER (AS COPPER SULPHATE) 2000MCG / FOLACIN (AS FOLIC ACID) 500MCG /VITAMIN B12 10MCG /VITAMIN B6 5MG
5. Approval number of Complementary Medicine: 2024/CM0411
6. Shelf Life of Complementary Medicine in months: 24 MONTHS WHEN STORED BELOW 30°C IN AN ALU/PVC BLISTER PACK, PACK SIZE 2 X 15'S
7. Category for distribution of Complementary Medicine: PHARMACY COMPLEMENTARY MEDICINES (PCM)
8. Name and address of manufacturer(s): CLAPS INDUSTRIES PVT. LTD, PLOT NO. 608, GIDC, SANAND-II, INDUSTRIAL ENTATE, HIRAPUR, SANAND, AHMEDABAD, GUJARAT-382110, INDIA
9. Name and address of principal: CLAPS INDUSTRIES PVT. LTD, B-1202, INFINITY TOWER, 60 FEET ROAD, PRAHLADNAGAR, TALUKA: VEJALPUR, DISTRICT: AHMEDABAD 380 015, GUJARAT, INDIA
10. Name and address of applicant: CLAPS INDUSTRIES PVT. LTD, B-1202, INFINITY TOWER, 60 FEET ROAD, PRAHLADNAGAR, TALUKA: VEJALPUR, DISTRICT: AHMEDABAD 380 015, GUJARAT, INDIA
11. Address at which certificate will be kept: CLAPS INDUSTRIES PVT. LTD, B-1202, INFINITY TOWER, 60 FEET ROAD, PRAHLADNAGAR, TALUKA: VEJALPUR, DISTRICT: AHMEDABAD 380 015, GUJARAT, INDIA
12. Date of Original Approval: 27 MARCH 2024
13. The complementary medicine will be: IMPORTED INTO ZIMBABWE
14. Conditions of Approval imposed by Authority: see annexure
15. Date of issue of certificate: 27 MARCH 2024
16. Issued at Harare this 27th day of MARCH 2024

[Signature]
Director - General

This certificate must be returned to the Authority if cancelled, invalidated or if the registration of the medicine is withdrawn or when requested to do so by the Director General. Failure to do so is an offence.

CERTIFICATE
Approval

Written by: <i>[Signature]</i>	Approved by HoU/HoD: <i>[Signature]</i>	Authorised for use by QM: <i>[Signature]</i>
Date: 05/09/2025	Date: 02/04/2025	Date: 17/04/2025

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Certificate of a
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Date of expiry of registration: 26 MARCH 2029

GENERAL CONDITIONS

1. Compliance with labelling requirements;
2. Subject to renewal of registration every five (5) years on condition of demonstration of quality, safety, and efficacy;
3. Mandatory reporting of individual case safety reports (ICSRs) that includes (ADRs, AEs, SAEs, & AEFIs) and/or product defects;
4. Applicant and/or manufacturer is required to have a functional pharmacovigilance system in place for their medical products;
5. Applicant and/or manufacturer is required to designate a responsible qualified person for pharmacovigilance (QPPV) to be in charge of the pharmacovigilance system for the applicant;
6. Periodic safety update reports (PSURs) and periodic benefit risk evaluation reports (PBERs) are generated for innovator products and biological products. For generic products, these should be generated if there are safety concerns¹;
7. Compliance with any request by the Medicines Control Authority of Zimbabwe to conduct post-authorisation safety and efficacy studies whenever the need may arise.

NB: Please note that the conditions stated above, in this annexure are also part of the legal provisions for existence of a national vigilance systems based on requirements for section 33, section 33(2) (iii), 33(3) and 29 (1)(b) of the Medicines and Allied Substances Control Act (MASCA) [Chapter 15:03], MCAZ National Pharmacovigilance handbook 2016 Edition, MCAZ circular 1/2000 dated 21st March 2000, MCAZ Pharmacovigilance Guideline for Pharmaceutical Industry MCAZ/PVCT/GI-02 dated 3rd March 2021, Guideline for Pharmacovigilance of COVID-19 Vaccines MCAZ/PVCT/GI-03, dated 11 June 2021, and Zimbabwe National Adverse Events Following Immunization (AEFIs) Guideline 2017.

¹ Risk management plan, pharmacovigilance plan in line with International Conference of Harmonisation (ICH E2A), periodic safety update reports (PSURs) and periodic benefit risk evaluation report (PBERs) is a format of safety report described by the ICH E2C (R2) guideline which is used as a basis for the PSUR. The report is produced by the manufacturer and/or applicant at defined time points after a chemical entity, innovator medicine including vaccine has been registered in Zimbabwe in line with other regulatory international requirements. The report is to provide comprehensive and up-to-date information about the safety of a medicine. The report needs to summarise any new evidence on safety, efficacy and effectiveness that might affect the balance of risks and benefits. It provides details about the risks to regulatory authorities and identifies where risk management initiatives may be required.

Written by: <i>A. Mawera</i>	Approved by HoU/HoD: <i>P. Mawera</i>	Authorised for use by QM: <i>[Signature]</i>
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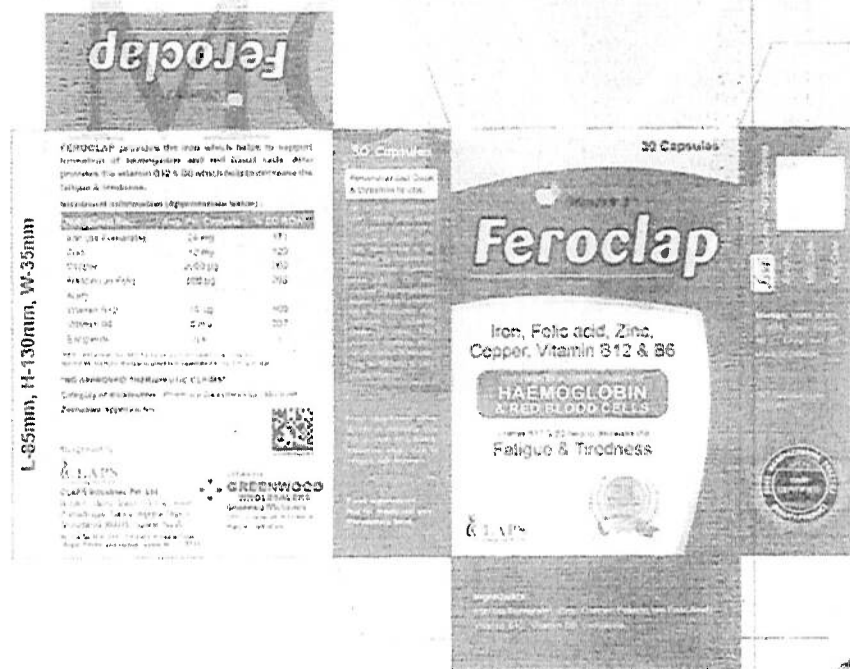
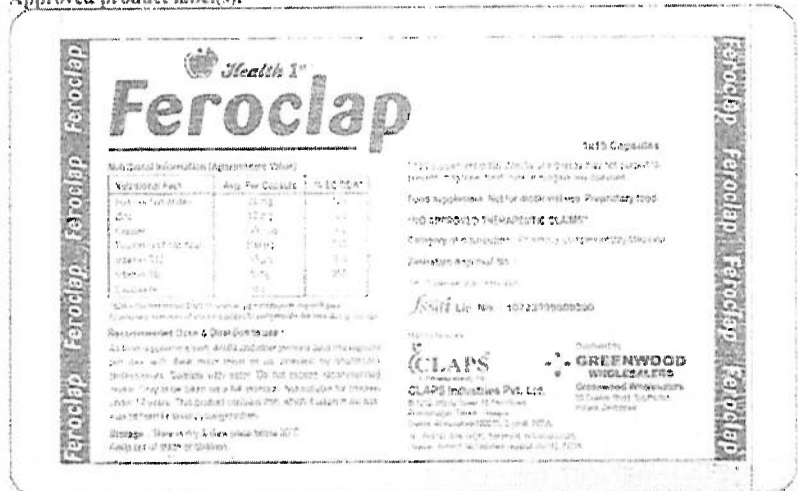
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Approved product label(s):



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Date: 08/09/2025	Date: 08/09/2025	Date: 08/09/2025